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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,564	08/31/2001	Andrew K. Benson	50046490-0002	2451
21125	7590	02/24/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP				MARTINELL, JAMES
WORLD TRADE CENTER WEST				
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BOSTON, MA 02210-2604				1631
ART UNIT				PAPER NUMBER

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SJM

Office Action Summary	Application No.	Applicant(s)	
	09/945,564	BENSON, ANDREW K.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-19, 21-25 and 29-36 is/are pending in the application.
 - 4a) Of the above claim(s) 34-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-19, 21-25, and 29-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

Claims 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Applicant's election with traverse of the requirement for restriction in Paper No. 12 is acknowledged. The traversal is on the ground(s) that applicant does not believe that it would not be an undue burden to search the methods of Groups I and II. This is not found persuasive because the methods of Group II are far broader than the methods of Group I which methods are limited to analysis nucleic acid molecular hybridization assays on microarrays.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "representative genomic microarray" (claim 16) is vague and indefinite because the instant application does not distinguish between a representative genomic microarray and a non-representative genomic microarray.
- (b) The recitation of "representative microarray" (claims 16, 17, 19, and 20) is vague and indefinite for reasons given in (a) above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1631

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19, 21-25, and 32 are rejected under 35 U.S.C. 102(a), (b), and (e) as being clearly anticipated by any one of Gingeras et al (Genome Research 8 (4), 435 (1998)), Salama et al (Proc. Natl. Acad. Sci. USA 97 (26), 14668 (2000)), or Chee et al (WO 95/11995 (May 4, 1995)). Gingeras et al teaches the genotyping of bacteria by nucleic acid molecular hybridization assays on microarrays (e.g., see the Abstract) for purposes of species identification (e.g., page 438 and Figure 3) and utilizing fluorescent dyes (e.g., page 446, column 1). Salama et al teaches the detection of *Helicobacter pylori* by genome comparisons using nucleic acid molecular hybridization assays on microarrays (e.g., pages 14671-14673) using fluorescent dyes (e.g., pages 14669-14670). Chee et al teaches analysis of genetic polymorphisms by nucleic acid molecular hybridization assays on arrays (e.g., Abstract; pages 18-19, 30, 102, and 118-120; and the Claims) using fluorescent dyes (e.g., page 90). The claimed methods embrace each of the disclosures in each of the references. This rejection is repeated for reasons already of record (e.g., Office action mailed July 28, 2003, paragraph bridging pages 3-4). Applicant's arguments (response filed December 1, 2003, pages 7-8) are not persuasive because applicant does not argue each

Art Unit: 1631

of the rejections separately and with specificity and does not argue the references in the manner in which they were used in the rejection.

Claims 16-19 and 21-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eisen et al (Proc. Natl. Acad. Sci. USA 95: 14863 (1998)). Eisen et al teaches the genotyping of yeast by nucleic acid molecular hybridization assays on microarrays (*e.g.*, Abstract and Results and Discussion sections) using fluorescent dyes (*e.g.*, page 14864, column 1). The claimed methods embrace the methods taught in Eisen et al. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed July 28, 2003, page 4). Applicant's arguments (response filed December 1, 2003, pages 7-8) are not persuasive because applicant does not argue each of the rejections separately and with specificity and does not argue the references in the manner in which they were used in the rejection.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Gingeras et al (Genome Research 8 (4), 435 (1998)), Salama et al (Proc. Natl. Acad. Sci. USA 97 (26), 14668 (2000)), or Chee et al (WO 95/11995 (May 4, 1995)) in view of Berno (U.S. Patent No. 6,223,127 (April 27, 2001)). The discussion of each of the primary references hereinabove is incorporated here. Berno discloses mathematical methods for the analysis of relatedness of nucleic acids based on hybridization assay data (*e.g.*, see Abstract, Figure 5-9, and columns 6-8). It would have been obvious for one of ordinary skill in the art at the time the invention was made to analyze genome comparisons based on nucleic acid molecular hybridization assay results from microarrays as taught in any one of the primary references in the manner taught by Berno in order to more readily identify genomic similarities and differences as suggested by Berno (*e.g.*, Abstract and first full paragraph in column 2). This rejection is repeated for reasons already of record (*e.g.*, Office action mailed July 28, 2003, page 4). Applicant's arguments (response filed December 1, 2003, pages 7-8) are not persuasive because applicant does not argue each of the rejections separately and with specificity and does not argue the references in the manner in which they were used in the rejection.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Gingeras et al (Genome Research 8 (4), 435 (1998)), Salama et al (Proc. Natl. Acad. Sci. USA 97 (26), 14668 (2000)),

Art Unit: 1631

or Chee et al (WO 95/11995 (May 4, 1995)) in view of Berno (U.S. Patent No. 6,223,127 (April 27, 2001)) as applied to claims 16-31 above, and further in view of applicants' admitted state of the prior art (instant application, page 3, line 8-page 6, line 19; page 1, line 22; page 2, line 5; and page 7, lines 3-16). Applicants acknowledge each of the bacterial species mentioned in claim 33 to be old and of interest in industry and medicine. It would have been obvious for one of ordinary skill in the art at the time the invention was made to analyze the genetic material of the admittedly old and admittedly important bacteria in the manner discussed in the previous rejection. This rejection is repeated for reasons already of record (e.g., Office action mailed July 28, 2003, paragraph bridging pages 4-5). Applicant's arguments (response filed December 1, 2003, pages 7-8) are not persuasive because applicant does not argue each of the rejections separately and with specificity and does not argue the references in the manner in which they were used in the rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**